DATA EVALUATION RECORD

INDOLE
(Bull Run Fly Attractant)

STUDY TYPE: Waiver Requests for Mammalian Toxicity Testing Requirements

MRID 47396921

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Prepared by
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Task Order No. 08-031

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EPA Secondary Reviewer:

STUDY TYPE:	Waiver Requests for Mammalian Toxicity Testing Requirements
MRID NO:	47396921
DECISION NO:	392213
DP BARCODE:	DP353134
TEST MATERIAL:	Indole
PROJECT STUDY NO:	Not applicable
SPONSOR:	Bull Run Scientific, VBT, 7400 Beaufont Springs Drive, Suite 300, Richmond, VA 23225-5519
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Indole: Tier I Mammalian Toxicology
AUTHOR:	Smith, C.A.
STUDY COMPLETED:	April 2, 2008
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The study is descriptive in nature, and not subject to the requirements of 40 CFR Part 160.
CONCLUSION:	The information provided is sufficient to grant the requested waivers for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation, Acute Dermal Irritation, Dermal Sensitization, Hypersensitivity Incidents, and Prenatal Development for indole. Additional justification is needed for waivers of Bacterial Reverse Mutation Assay, *In vitro* Mammalian Cell Assay, and *In vitro* Mammalian Chromosome Aberration testing.

need further justification

Test Material

Indole (present at 0.2% w/w in Bull Run Fly Attractant)

Product Description

Bull Run Fly Attractant is an end use product to be used as an attractant for "filth flies" such as house flies, blow flies, bottle flies, lesser house flies, cluster flies, lance flies, secondary screwworm flies, flesh flies, and false stable flies. The product is composed of a fly attractant mix (97.3% w/w) in a [redacted]
Indole is present in the product at a concentration of 0.2%. The pouch of attractant is contained in a disposable or reusable trap that is filled with the appropriate amount of water and hung in the treatment area.

Waiver Request

The registrant is requesting waivers for the following requirements:

Acute Oral Toxicity	(OPPTS 870.1100)
Acute Dermal Toxicity	(OPPTS 870.1200)
Acute Inhalation Toxicity	(OPPTS 870.1300)
Acute Eye Irritation	(OPPTS 870.2400)
Acute Dermal Irritation	(OPPTS 870.2500)
Dermal Sensitization	(OPPTS 870.2600)
Hypersensitivity Incidents	(OPPTS 885.3400)
Prenatal Development	(OPPTS 870.3700)
Bacterial Reverse Mutation Assay	(OPPTS 870.5100)
In vitro Mammalian Cell Assay	(OPPTS 870.5300)
In vitro Mammalian Chromosome Aberration	(OPPTS 870.5375)

Registrant's Justification

Bull Run Fly Attractant is packaged in unit doses. The largest proposed net weight for the attractant is 69.97 g. Since the attractant nominally contains 0.2% indole, the largest proposed package size of the product would contain 0.14 g of indole.

Acute Oral Toxicity

According to the supplier's MSDS, the acute oral LD_{50} for indole in rats is 1000 mg/kg.

Acute Dermal Toxicity

According to the supplier's MSDS, the acute dermal LD_{50} for indole in rabbits is 790 mg/kg.

Acute Inhalation Toxicity

Assuming the maximum label use rate of 48 traps/acre, and an instantaneous and simultaneous release of 100% of the indole from the traps into a volume of air 10 feet high in one acre, the indole concentration would be 8.3×10^{-7} mg/L of air:

(48 traps/acre) x (69.97 g attractant/trap) x (0.2 g indole/100 g attractant) = 6.7 g indole/A

(43,560 ft^2/A) x (10 ft) = 435,600 ft^3

(435,600 ft^3) x (0.0283 m^3/ft^3) x (1,000,000 cm^3/m^3) x (1 L/1000 cm^3) = 1.233×10^{10} L of air

6.7 g indole/1.233×10^{10} L of air = 8.3×10^{-10} g indole/L of air = 8.3×10^{-7} mg indole/L of air.

This calculation is a worst-case assessment; in a realistic case, the indole would be released over time and be dissipated by wind. Therefore, there is no significant inhalation exposure to indole

from the use of Bull Run Fly Attractant. During production of the product, there is no significant worker exposure to indole due to engineering controls and the use of appropriate PPE.

Acute Eye Irritation

No significant ocular exposure to indole associated with the use of Bull Run Fly Attractant is anticipated. The attractant is packaged in a water-soluble pouch that is not to be opened by the user. The trap opening into which the water is added to dissolve the pouch containing the attractant is small in proportion to the overall trap size. Since the attractant suspension is not sprayed, there will be no spray drift. During manufacture of the product, workers are protected by engineering controls and the appropriate PPE.

Acute Dermal Irritation/Dermal Sensitization

No significant repeated dermal exposure to indole associated with the use of Bull Run Fly Attractant is anticipated. The attractant is packaged in a water-soluble pouch that is not to be opened by the user. The trap opening into which the water is added to dissolve the pouch containing the attractant is small in proportion to the overall trap size. Since the attractant suspension is not sprayed, there will be no spray drift onto the user's skin or clothing. During manufacture of the product, workers are protected by engineering controls and the appropriate PPE.

Hypersensitivity Incidents

The registrant is not aware of any hypersensitivity incidents associated with indole. Should the registrant become aware of hypersensitivity incidents, they will be reported to the Agency.

Prenatal Development

No significant oral, dermal, or inhalation exposure to indole is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirement for prenatal development should be waived.

Bacterial Reverse Mutation Assay

No significant oral, dermal, or inhalation exposure to indole is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirement for a bacterial reverse mutation assay should be waived.

In vitro Mammalian Cell Assay/*In vitro* Mammalian Chromosome Aberration

No significant oral, dermal, or inhalation exposure to indole is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirements for an *in vitro* mammalian cell assay and an *in vitro* mammalian chromosome aberration assay should be waived.

Reviewer's Comments

The reviewer believes that sufficient information was provided to grant the requested waivers for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation,

Acute Dermal Irritation, Dermal Sensitization, Hypersensitivity Incidents, and Prenatal Development. Since even a minute quantity of a chemical can be genotoxic, additional justification is needed for waivers of Bacterial Reverse Mutation Assay, *In vitro* Mammalian Cell Assay, and *In vitro* Mammalian Chromosome Aberration testing.